IN THE UNITED STATES DISTRICT COURT

IN AND FOR THE DISTRICT OF DELAWARE

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AVENTIS PHARMA S.A., SANOFI-AVENTIS U.S., LLC,	:	Civil Action
Plaintiffs,	:	
v.	:	
HOSPIRA, INC., APOTEX,INC., and APOTEX CORP.,	:	
Defendants.	:	07-721-GMS (Consolidated)

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Wilmington, Delaware
Wednesday, September 30, 2009
10:00 a.m.
Pretrial Conference

- - -

BEFORE: HONORABLE GREGORY M. SLEET, Chief Judge

APPEARANCES:

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Ashby & Geddes
-and-
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THE COURT: Good morning

(Counsel respond "Good morning.")

THE COURT: Please take your seats. This is an office conference. As such, we will suspend the formalities of the regular session of Court. Counsel, however you feel comfortable having a discussion with me, whether that's rising or being seated, I am comfortable with whatever you choose. I know lawyers are used to being up and sometimes just more comfortable in that setting. But I have taken the podium away from you, so you can't get me there, at least.

Let's start with introductions. Delaware counsel.

MR. BALICK: Good morning, Your Honor. How are you today?

THE COURT: Fine, thank you, Mr. Balick.

MR. BALICK: Steven Balick from Ashby & Geddes for the plaintiffs. My co-counsel, starting from Your Honor's right, some of whom you have met and some of whom you probably have not, George Pappas, Christopher Sipes, Michael Kennedy, and Kevin Collins, all from Covington & Burling.

THE COURT: Good morning.

Who is going to do the honors?

MS. MATTERER: Your Honor, good morning. For Hospira, Inc., I have from the law firm of Winston & Strawn

James Hurst, and Imron Aly, and, also, Jovial Wong, and my partner from Morris James, Richard Herrmann, is here.

THE COURT: Good morning, Mr. Herrmann.

MR. FOLT: Good morning, Your Honor. Dan Folt for Apotex, joined by my partners today from various offices, our lead counsel Art Dresner to my left from our New York office, Rich Ruzich from our Chicago office, Kerry McTigue from our Atlanta office, and we brought Matt Mousley from our Philadelphia office. Thank you.

THE COURT: Good morning.

I want to say something. I want it to be understood in the spirit in which it's intended, that is, constructive criticism, and not coming down on the heads of the lawyers or being angry or anything like that.

I was teaching last night one of the courses at one of the two law schools I teach at, patent litigation. I don't remember the question that it was that I posed to the student who responded, but he said, Well, it's because the lawyers want to maintain their credibility. And I said, well, that's not exactly responsive to the point that I am trying to get you to, but let me digress a little bit here. And I did for some time, actually.

The ultimate point that I was trying to make was that lawyers who appear in any American courtroom, that the most valuable and most important currency that you have to

trade on is your credibility. And I posited to the students how vital it was that they, as young lawyers, and as they moved on into their practices, were scrupulous in spending it wisely, spending that currency wisely.

I have to comment here today that I am not exactly of the opinion that the currency that you have -- and I must say, particularly on the defendants' side of the table -- has been spent as well as it could have been insofar as the motions in limine that have been filed.

I have ten -- 12, actually. And as my daughter says, "My bad," I will accept the fact that I left myself open to I think it's five a side from the defendants, I believe that's the count, and I wasn't clear and should have been clearer insofar as the limitations on that.

But I do recall, I think, at least I would imagine that I probably did, and I do in most Bench trial settings, try to urge upon counsel the thought that it is a Bench trial, and therefore, it seems to me that spending a lot of your time and your clients' money and my time going through motions that probably would be better left for another day, issues that can be preserved in another way, and quite frankly, are probably better addressed after hearing testimony in some instances. That seems to have somehow gotten lost here.

I promise you that you are swimming decidedly

upstream on these motions. I will entertain them probably in brief. But I wanted to say that, again, for whatever it's worth. I am going to keep saying it, over time, about a variety of things, because, quite frankly, I and my colleagues, and I think it's fair for me to say that I speak for them, are lamenting at various times in conversations among ourselves the current state of affairs out there in the land with regard to litigation practice. And maybe we are a little more sensitive to it here in Delaware because of the now extended period of vacancy that we have and our very heavy, complex civil litigation docket, matched up against, or at least it butts up against the dictates of the United States Constitution insofar as our criminal case responsibilities, and how difficult it is and has become for us to juggle that.

This is not your problem. But you do need to be aware of it and act accordingly, I think, not to the detriment of your clients or preserving your positions that you must preserve. And you are here to win. Look, I know that. This is what you are here to do. You are here to win your clients' case. None of the Judges are naive about that.

Enough said on that subject. I want to start out with the plaintiffs' motions.

I will just call out the title and the docket

item. 262 is the opening, is the motion and opening brief. It's styled No. 1, a Motion to Preclude Defendants from Relying on a "Prior Public Use" Invalidity Defense.

Mr. Pappas.

MR. PAPPAS: Your Honor, if you will, we have divided up the responsibilities.

THE COURT: You get to do that. You get to divide them up. It's just me and my young man here. That's it.

MR. PAPPAS: We are well aware of it, Your Honor. That is why we limited ourselves to two. Also, we have divided them up so we can attempt to address them, to the extent you take them up, in as brief and in as succinct a fashion as possible.

It will be divided into Mr. Collins, Mr. Sipes and I, as you call them out, if that is permissible, Your Honor.

MR. COLLINS: Good morning, Your Honor. I will be handling this motion. It is pretty straightforward.

In the reply, the third round of reports from the experts on the defendants' side, they interjected a public use invalidity defense for the first time in this case. There is no reason to do that.

Had we known about that prior to that, there would have been fact discovery on this issue. It's a

specific invalidity defense.

Our inventor testified in April 2009 that he was relying on these clinical trials that existed and took place prior to the filing of the application. We produced our NDA that showed these clinical trials. And we produced this NDA to the defendants in June 2008.

They were well aware of these facts.

So for the first time they interject this defense in the third round of reports. There has been no fact discovery on this. There is an experimental use exception to the public use. There is fact discovery that hasn't been taking place. There is no expert reports on this.

THE COURT: So the first time you heard about it was in the rebuttal?

MR. COLLINS: That's correct. The third round of reports, Your Honor.

So it is pretty straightforward. It is too late to come into the case. And we would ask Your Honor to enter an order precluding either defendant from interjecting this into the trial.

THE COURT: Who is going to respond?

MR. HURST: Actually, all we are doing is pointing out the natural consequence of a position their expert took for the first time in rebuttal. That is all we

are doing.

Our position here, Your Honor, is that the claims require a formulation that can be administered without causing anaphylactic manifestations. Our position is, they didn't teach or enable that. That is our position. We weren't arguing that this had been used in the past as a prior public use, because, in fact, we don't think that even today these formulations are capable of being given without causing anaphylactic manifestations. In fact, you have got to load the patient up with steroids in advance. There has got to be a crash cart next to the patient before you can give this drug to them, because, in fact, to give this drug risks anaphylactic manifestations. So we don't think they have ever taught or enabled it.

In response to that argument, their expert in rebuttal says, yes, we did, and we proved it during the clinical trials. He said, as of July 1991, the priority date, he says, we proved this as of July of 1991. If that is true, Your Honor -- and we don't believe it is true -- but if his argument is true, then, necessarily, it's a prior public use, because he said he proved it, they proved it during clinical trials.

Once it's proven, the experimental use exception that Mr. Collins raised is gone.

So their expert has said, we proved it in July

of 1991; therefore, these clinical trials, once he says they proved it, they are no longer experimental use, and that becomes a prior public use.

All we are doing, Your Honor, is literally taking his argument at face value and saying, look, if you are actually right about that, your patent is invalid for a different reason. That is the only argument we are making. It is entirely contingent on the argument that their expert makes.

MR. COLLINS: Very quickly, Your Honor.

Hospira doesn't dispute that this was not interjected into the case until the third round of reports. It is a fact-intensive inquiry. It would require third-party discovery that did not take place in this case because it was not advanced in fact discovery.

Again, the Federal Circuit is very clear: The test for public use, from close consideration of evidence, relevant to experimentation, the nature of the activity that occurred in public, public access to the use, confidentiality obligations imposed on members of the public who observed the use, and commercial exploitation.

So no fact discovery on that, because it was raised in the third round of expert reports. Accordingly, it should not be in the case.

THE COURT: Apart from the point you just made,

you need to respond to that, because this is a notice issue and prejudice that is claimed as a result of the lack of notice.

MR. HURST: The lack of notice arises from the fact that all we are doing is commenting on an argument that was made literally for the first time in the rebuttal report, Your Honor.

THE COURT: You are saying they should have known that you were going raise this defense.

MR. HURST: No. They should have realized that the consequence of the argument they were making is they jeopardize the validity of the patent. They raised for the first time in July of 1991 is when they proved it. They said we proved in July of 1991 --

THE COURT: But is it right or is it not that the first time the plaintiff was put on notice as to this particular position was in the third round of reports?

MR. HURST: That is true, Your Honor.

THE COURT: How --

MR. HURST: My response is, I am only raising the argument as a contingency. If their expert literally gets up on the stand, Your Honor, and says, We proved this fact by July of 1991, I will say: If so, the clinical trials were ongoing and public after that. Right?

I think as a matter of law the experimental use

doctrine is gone as soon as they say they proved it. They did make that claim for the first time.

THE COURT: Why don't you react to that.

MR. COLLINS: Your Honor, there is a lot of evidence that hasn't been taken on this public use and the experimental exception to it, and it would require third-party discovery that we couldn't take because we didn't know it was in the case.

THE COURT: He is saying that your expert introduces this issue.

MR. COLLINS: Actually, I would disagree with Mr. Hurst on that, Your Honor. Our inventor testified, Mr. Fabre, in April 2009. He was asked the question by Hospira's counsel: What is the proof that you have in July 1991 that this statement in the specification was true that this formulation would reduce the anaphylactic manifestations?

He said, Because in July 1991, at that time, this was the patent that was filed with the clinical trials --

THE COURT: Slow down, counsel.

MR. COLLINS: I am sorry. The bottom line is, the inventor testified that the clinical results he was referring to that occurred without pre-administration of steroids as of July 1991 occurred much earlier than that, in

1990 and before that.

So the defendants were put on notice that these clinical trials existed, but they never interjected it into the case. Again, there is issues about commercial exploitation, whether that was done for commercial exploitation, whether there is an experimental use to that. Again, none of that fact discovery has taken place.

It wasn't as if our experts interjected this for the first time. The inventor told them that in April 2009. In addition to that, our NDA told them that when we produced it in June 2008.

MR. HURST: Two facts. Those clinical trials were ongoing, which is what the inventor referred to. He said these were ongoing trials and they continued past the critical date. And the NDA says the same thing. The clinical trials passed over July of 1991.

So the position that we understood Sanofi was taking is that they proved this fact -- and we disagree with it, but that's their position -- they said they proved that you could give these formulations without anaphylactic manifestations through these clinical trials, which ended after July of 1991. Their expert, as we understood it, was coming up with a new position, that, No, no, no. We proved it midway through the clinical trials as of 1991.

And really all we are doing -- it will be a

short examination. If he says, We did prove it through these public clinical trials before July 1991, all those factors, all that discovery is out the window because there is no more experimental use exception.

THE COURT: Is there a way to limit the inquiry so as to give you the protection that you are looking for, because of the absence of fact discovery on this particular issue?

MR. COLLINS: No, Your Honor, because what we would do is we would issue subpoenas to third-party institutions that actually conducted these clinical trials, see the protocols they used, see how much control sanofi-aventis had on it to conform to an experimental use exception to the public use defense. We would find out from patient records what the patients were told with respect to the claimed formulation.

This notion that somehow we advanced a legal argument, somehow that turns into an entire independent invalidity defense, is just not appropriate.

THE COURT: Your colleague...

Turnabout will be fair play.

MR. SIPES: I am wondering if maybe we can work this out. This is our understanding, if I was a little confused. What the inventor said was that, in his view, the Phase 1 trial was an experimental use that enabled him to

determine that he believed his formulation was successful. So he was making clear in his view it was experimental use. That is, he was using it to determine whether it had suitable properties.

But the fact is, on experimental use -- and they did not at that time challenge it as public use as opposed to experimental use, that is, the confidentiality, the fact that we controlled the protocol or whatnot.

If they will agree that it meets the requirements for experimental use, and their sole issue on public use is the inventors' reliance on it in order to determine the expectation that it had suitable properties, and then they argue that that mere fact makes it a public use, we can live with that.

What we don't want is them coming in and now saying it was otherwise public -- I mean, obviously, we agree that they are publications, they have been around in publications. But the tests themselves were public, it seems to us, unfair.

THE COURT: Can you accept -- I am going to cut it off here. If you can accept it, you can. If you can't, you can't. Because I am not going to let you introduce a new basis for contending invalidity based on a rebuttal report. You just can't lay in the woods to do that.

MR. HURST: Frankly, I didn't quite follow what

he said, so I can't accept it. But can I talk to him later?

THE COURT: Sure. And I am going to require, if you are able to reach an accord, I am going to need it written down in specific terms in a stipulation.

MR. HURST: Thank you, Your Honor.

THE COURT: I am going to grant the motion conditionally, upon hearing further from counsel, because I think that the underlying reason for the motion is meritorious.

That is the ruling.

MR. HURST: Thank you, Your Honor.

MR. COLLINS: Thank you, Your Honor.

THE COURT: Then we have at Item 263, Plaintiffs' Motion No. 2, To Preclude The Defendants From Presenting Unpled Inequitable Conduct Allegations. I just want you to, in talking about this, keep in mind Rule 15 and its liberal policies -- its directive that courts should liberally amend, permit liberal amendments even during and after trial.

MR. COLLINS: Your Honor, again, Kevin Collins for the plaintiffs on this motion.

Again, the Federal Circuit -- and I heard Your Honor with respect to Rule 15 and I know leave is to be freely granted. But at some point the target has to stop for us to put on a defense to inequitable conduct.

The Federal Circuit requires, and most recently in this Exergen case, where they talked about the heightened standard for inequitable conduct, it must be pled with particularity.

THE COURT: Indeed.

MR. COLLINS: Even after Your Honor granted Hospira's motion that was filed in June, most recently, on September 17, there was an order allowing Hospira to amend its counterclaim to add two additional specific allegations of inequitable conduct.

We are not talking about this.

There has been new allegations placed into the proposed findings by Hospira and Apotex. They are not tied to any amended pleading or any counterclaim. There is allegations in interrogatory responses that we are concerned about.

Again, we are going to trial in three and a half weeks, and we are trying to prepare witnesses. Our witnesses haven't prepared opinions on this because they haven't been part of the case.

I understand, Your Honor, with respect to Rule 15, but --

THE COURT: I didn't say that to signal a view.

MR. COLLINS: Your Honor, I have a chart prepared. I am happy to get into details. But the only way

I could figure it out was with a color-coded chart. The yellow line up at the top indicates the allegations that are properly of record in a counterclaim. At the time we filed the pretrial order, Apotex went on and filed another motion for leave to amend to add additional inequitable conduct allegations.

The excuse that Apotex has proffered in its motion is that they just took the deposition of one of the prosecuting attorneys. I would suggest to Your Honor, there is not a single fact in that deposition that gives rise to inequitable conduct. Indeed, the allegations they raise related to a Gueritte-Voegelein article that you will hear a lot about at trial, and as part of the invalidity case, there was not a single deposition question asked to the prosecuting attorney: Were you ever in possession of this?

The inventors were never questioned about this. And somehow they are just going to put it into the case.

So there is a lot of unpled inequitable conduct allegations in interrogatory responses, in proposed findings, that don't find and are not tied to counterclaims.

We would ask, rather than going through specifics -- and we are happy to do that -- just that an order be entered precluding either defendant from advancing inequitable conduct allegations that aren't in a pleading of record as of this moment.

MR. ALY: Your Honor, there are two defendants, so I will let Apotex speak for Apotex.

But on behalf of Hospira, Mr. Collins made some points. A large part of them are moot as to Hospira because they were in an amended complaint -- amended counterclaim, and Your Honor has granted the amended counterclaim.

THE COURT: I think I recall reading that.

MR. COLLINS: Your Honor, we certainly don't contest what Your Honor allowed in the most recent order. No dispute there.

MR. ALY: Your Honor, that leaves two little pieces. The issue as to these two little pieces is that they were in our interrogatory responses on the day that discovery ended. We make it a habit of supplementing those discovery responses. In this case that was May 29, 2009, which include all these defenses, the two defenses which they are talking about now. One relates to a Tarr prior art reference, and the other relates to a commercial catalog describing polysorbate 80, one of the ingredients that is at issue in the formulation.

THE COURT: These are the two he has contended are unpled allegations.

MR. ALY: Yes, Your Honor. These are the two so-called new defenses because they are not technically in the pleadings. We agree, those two are not in the

pleadings. But from a notice requirement point of view, they have had notice of them since then. Discovery was taken on them.

THE COURT: What was the second one?

MR. ALY: The second one was a commercial catalog.

THE COURT: The first was a Tarr prior art reference?

MR. ALY: Yes, T-a-r-r. Your Honor, discovery was taken about both of those. In fact, that's how we found out about the commercial catalog, through talking to the inventors and the different information they had.

As to the Tarr reference in particular, the experts have actually even addressed, both sides' experts have addressed that reference to talk about whether it is really material or not material in terms of inequitable conduct.

So there has been discovery. There has been opportunity for it. In fact, the expert has already considered at least that one issue. If they didn't consider the separate one, that was their choice. It was also -- the commercial catalog was the Seppic catalog. That was also in our reports, and they could have considered that. I am talking about our opening reports, the first round that we submitted in this case through expert discovery.

For those two, they are not in the complaint, but plaintiffs had been on notice of them. So if it is a matter of a slight modification just to include those two in addition to what is already there, that is sufficient.

Thank you, Your Honor.

THE COURT: Let me deal with just Hospira for a moment here.

MR. COLLINS: What Mr. Aly said was generally accurate. These specific allegations of Tarr and these other commercial catalogs were in the May 29th interrogatory responses. Hospira subsequently filed their motion for leave in June and didn't add those. So they chose to add specific allegations --

THE COURT: The question is, apart from the failure, which he concedes, the Rule 9(b) failure, what is your reaction on the issue of fairness?

MR. COLLINS: On the issue of fairness, Your Honor, they weren't in the case when we were doing our expert reports.

THE COURT: Has there been discovery on them? Have the experts addressed the Tarr reference?

MR. COLLINS: Validity, yes, Your Honor. Materiality, no. Validity, these references are in the case for validity, no question about it. But in terms of materiality and cumulativeness, we never had a chance to

address that.

So, yes, they are in the case, but for a different issue.

THE COURT: Counsel, I think you were referring to a May 29th supplemental response to an interrogatory as to -- what was the specific thing you were responding to?

MR. ALY: Interrogatory defenses, including inequitable conduct, and those were included among those defenses. That's correct.

MR. COLLINS: I agree, Your Honor, they were in the interrogatory responses. Hospira then moves and doesn't include them. We don't put them in our expert reports because they are not part of the case yet at that point. There was certain --

THE COURT: What would be necessary to enable you to not feel disadvantaged at this point?

MR. COLLINS: I guess perhaps a supplemental expert report.

I would like to, actually, if I could confer.

THE COURT: Sure.

MR. SIPES: What we don't want to hear, then -- we need to prepare for trial. We don't want to go back --

THE COURT: I don't want to set you off on new discovery larks and that kind of thing. Go ahead.

MR. SIPES: We don't want to be hearing from

them, Oh, this isn't in your expert report, when we have tried to respond to allegations that, while they put them in the May 29 interrogatory responses, they didn't then, when they decided to amend to say what they are going to add to their pleadings, they chose not to put them in their request to amend.

As long as we are not hearing from them: That is not in your expert reports. For these two, that's probably all right.

THE COURT: Fair enough.

Your response, Mr. Aly?

MR. ALY: Your Honor, I am holding their expert report.

THE COURT: Respond to his point directly. He doesn't want to be confronted with an objection, Well, Judge, that's not in their expert report.

MR. ALY: It was the other way around, Your Honor. And I apologize. Maybe I was excited, because when I heard them to say that this wasn't argued in the expert reports, I am holding one of their expert reports, Kinam Park, and they are addressing that point.

So the supplementation, they already have done it. They have already addressed this point specific to inequitable conduct, not just for relevancy. It says, The Tarr emulsion article is not material, under the heading

There Was No Inequitable Conduct in the expert report of Kinam Park, one of their seven experts.

Maybe I was mistaken, Your Honor. I was excited about that.

MR. SIPES: Your Honor, this is the problem, that it is a small field, and there are two Tarr articles. I think what you are referring to was the Tarr emulsion article, not the Tarr --

MR. ALY: There is the Tarr emulsion article and then there is the Tarr and Yalkowsky reference that they are both referring to in that paragraph. The point that I was making, Your Honor, is these issues are already addressed in here.

There is another heading also that Sanofi Did Not Misrepresent Differences From the Tarr and Yalkowsky References, if you want to talk about that one as well, there is a section on it there.

MR. SIPES: What about the separate catalog issue?

MR. ALY: We were talking about Tarr. Now if you want to switch to the commercial catalog, there is a section on etoposide prior art is not material, the same arguments that you made there could apply to the catalog, because you are talking about the ingredients there, if that's what you want to talk about. They were in our

original reports all along. They had the opportunity.

MR. SIPES: If he thinks there is enough there that there won't be an objection and we have some latitude to respond, that is fine.

THE COURT: You will have that latitude.

Anything further you want to say?

MR. ALY: No, Your Honor.

THE COURT: So, then, I guess, for purposes of the record, I am going to deny this motion, conditioned upon the discussion that we have had, if counsel feel the need to file with the Court a stipulation to make clear what we have agreed on. But I don't want to have to mediate the stipulation, if you understand what I am saying. If you can't agree, the record will speak for itself, and we will maybe need to have another round of discussion at trial.

But that will be the -- Mr. Collins?

MR. COLLINS: Your Honor, one more point with respect to Hospira.

There are additional allegations of inequitable conduct that don't appear in their discovery responses, that aren't part of their counterclaim, that appear for the first time in their proposed findings that were just submitted. We presume those are off the table, because they were never even in discussion.

THE COURT: We have narrowed the discussion down

to two points. That is where it's going to rest.

MR. COLLINS: That is fine, Your Honor.

THE COURT: All right. So that ruling goes to Hospira.

MR. DRESNER: As to Apotex, none of the issues of inequitable conduct that we are raising are not tied to motions to amend pleadings appropriately. In the first instance, Your Honor has granted the motion to amend for Hospira, Apotex has filed a joinder in that motion, in conference with counsel for Sanofi that have indicated that they would oppose that joinder. But the only basis for opposing that joinder would be the same basis that they opposed it for Hospira. And I expect that would be granted as to Apotex as well.

In addition to that, there is only one other factor relating to inequitable conduct that Apotex seeks to raise. That relates to a reference known as the Gueritte-Voegelein reference.

As to that reference, Your Honor, we have also filed a motion to amend the pleadings. So it is a subject for a motion to amend. And that is consistent with Rule 15. Mr. Collins indicated that in our response we pointed out that we recently filed this amendment in view of the fact that we recently took the deposition of the attorneys that prosecuted the case.

And we wanted to do that. We wanted to wait and see what that deposition would reveal. In fact, it didn't reveal anything new. Mr. Collins is correct about that. But we owed it to everybody to make sure that that deposition was taken before we just went ahead and filed the motion.

Now that that is done, the motion is on file. It's tied to this reference. And in the spirit of Rule 15, we would expect that to be granted.

THE COURT: Mr. Collins.

MR. COLLINS: Very well. One of the reasons that Your Honor denied motion for leave to amend is if it's futile. If they haven't properly pled an inequitable conduct claim, then they shouldn't be allowed to bring it. The Gueritte-Voegelein reference, all that's alleged is it is not disclosed. There is no specific allegation as to who didn't disclose it, when, where, and for what purpose. So one of the reasons that Your Honor would deny a motion for leave to amend, particularly at this late date, is if it is futile.

If you look at, Your Honor, it is attached to the reply, the portion of the transcript that deals with Gueritte-Voegelein, it is highlighted, it is all of three pages. There is not a specific question in there that goes to inequitable conduct with respect to Gueritte-Voegelein.

THE COURT: This is the attorney?

MR. COLLINS: Yes, the prosecuting attorney, Mr. Tom Irving from Finnegan Henderson. If Your Honor looks at this, it doesn't make any sense how this testimony can somehow lead to an inequitable conduct defense.

THE COURT: He has conceded that point and agreed with you that this is not the reason they seek to amend.

MR. DRESNER: That's correct, Your Honor.

MR. COLLINS: So in the absence of a well-pled complaint, there was a specific intent to deceive the Patent Office by a specific person, material nondisclosure, that shouldn't be allowed at this point.

THE COURT: Why do you say that amendment at this point would be futile again?

MR. COLLINS: Because there has been no specific allegation as to who failed to disclose the material reference. All they have said is, the Gueritte-Voegelein reference was not disclosed to the Patent Office.

MR. DRESNER: Your Honor, that is a subject for the motion to amend. That is not a subject for the motion in limine.

THE COURT: Can we wrap them together? Is it possible for me to dispose of them together?

MR. COLLINS: Yes.

MR. DRESNER: Your Honor, our motion to amend contains what we believe are the adequate requirements under the Exergen case to satisfy the requirements for amending the complaint. We believe it is adequately pled. It is a proper motion.

THE COURT: So the essence of the motion to amend is what?

MR. DRESNER: Well, first of all, the authors of Gueritte-Voegelein were tied to the company of the inventors of the patents in suit. They were part of the same company. The inventors had reason to know about this. It was part of the background. It was part of the information.

THE COURT: It's the inventors in your motion, the new averments, that you would contend that failed to notify the PTO?

MR. DRESNER: That's correct.

MR. COLLINS: Your Honor, the inventors' depositions were taken. They had Gueritte-Voegelein in their possession, any they didn't even ask a specific question to these inventors whether they were in possession of that.

You know, they can plead it. But there is nothing to back it up other than the bare allegation.

MR. DRESNER: There is no prejudice, Your Honor, to having --

THE COURT: I am not hearing prejudice. I am going to cut to the chase here on this one. I am going to deny the motion as to Apotex as well.

MR. COLLINS: Your Honor, just to be clear, that is only with respect to Gueritte-Voegelein. If there is other references --

THE COURT: Yes --

MR. DRESNER: That is all we are asking for.

THE COURT: That is all he is asking for, is the GV reference.

MR. DRESNER: GV.

MR. COLLINS: Very well, Your Honor.

THE COURT: And, therefore, subsumed in that ruling is, if I didn't make it clear, I am going to grant the motion to amend as well. So I am assuming there is an order attached to that motion. We will find it.

MR. DRESNER: There is, Your Honor.

THE COURT: And I will enter it.

Okay. Let's go with Hospira's first. I think there is some duplication.

MR. HURST: We should have done a better job of coordinating, Your Honor, between Apotex and Hospira, and that by itself would have reduced our numbers. We should have done that.

Can I make a suggestion for streamlining

purposes?

THE COURT: Please do.

MR. HURST: First, Your Honor, your comments at the outset, thank you for those. I appreciate it, honestly. If, on behalf of Hospira, I can rely on the papers for three of my five motions and just argue two of them, the first two that we filed, by way of --

THE COURT: That is with regard to Dr. Kaler.

MR. DRESNER: That is the Apotex issues, Your Honor.

THE COURT: I have Apotex in front of me. I am sorry.

MR. HURST: By way of explanation if nothing else here, of our five motions, Your Honor, two went to the claim construction issue that we think Your Honor resolved. I just wanted to talk about those. Those are the ones I wanted to pursue.

The other two related to what we believe would be chunks of trial time. Here is one of our concerns. The other side has proposed, Your Honor, seven expert witnesses. I know from recent experience before Your Honor and, obviously, knowledge about how you handle trials, sometimes trial time gets crunched because your resources are limited.

So two of our motions were designed that I am going to rely on the papers, bioequivalence and secondary

considerations, really it was designed to -- we think we have good motions, to eliminate blocks of time. And I was concerned about time, which is why I personally authorized all five of our motions. So I take full responsibility.

But that was the reasoning. I was concerned about time for two of them, mostly because we have so many experts on the other side and I know that means I have to take a lot of time on my side of the chess clock for cross-examination. And it's concerning to us.

Our first motion was "essentially free of ethanol," Your Honor.

THE COURT: The way you style it is "To Preclude Sanofi's Experts From Testifying About Claim Construction." I am not going to let experts testify about claim construction. You know that.

MR. HURST: Yes, sir.

THE COURT: Go ahead.

MR. PAPPAS: Your Honor, if I may.

Counsel made a point about being concerned about time. We do, too. We will have a chance to address that with you. But before we hear -- I have to ask you to consider this -- before we hear any more about numerosity of experts, they have five, we have seven, and we will explain why.

But we have two opponents. I just want Your

Honor to be aware that these defendants filed expert reports that contained just under 1,000 pages of opinions, 927, to be exact.

With five experts, they filed 927 pages of opinions. That's what we have to defend against.

We, with seven, only filed 613.

I suggest those numbers speak for themselves in terms of who is slimming things down.

THE COURT: Okay. Duly noted.

To my point, because I think there are two motions.

MR. HURST: Two motions relating to claim construction issues.

THE COURT: To experts testifying about claim construction. That is just not going to happen.

MR. HURST: And the reason that we brought the motion is because the expert report is designed entirely around a claim construction that we view as completely contradictory to Your Honor's ruling from the Markman hearing. So that's why we believe it is important --

THE COURT: In what regard?

MR. HURST: Here is what happened.

There is two types of solutions at issue in the claims. One is a stock solution. That's just a concentrate. And Your Honor ruled that a stock solution is

essentially free of ethanol only if it has five percent or less ethanol. That came basically from the spec. I don't understand Sanofi to be challenging that ruling at all.

What you do with the stock solution is you just dilute it with water or some water-based solution, and then you get your perfusion, and you put it into the IV bag and you drip it into the patient.

They have the amount of ethanol. The stock solution has the same amount of ethanol as the perfusion because you are not adding any, the same absolute amount.

The point here of the invention allegedly was to avoid ethanol manifestations, demonstrations of drunkenness or impaired vision or whatever happens, the various things that happen when you drink too much ethanol.

Here were the competing claim constructions. Sanofi came to Your Honor and said that for a perfusion it can have up to two percent ethanol. Their experts are arguing the same thing, Your Honor. They are arguing it in a different way. But their experts are now saying we infringe because they are arguing that the claim construction allows for up to two percent ethanol in a perfusion. You declined at Markman to accept that, and instead what you did was you accepted our proposed construction with a slight modification.

We said that for a perfusion it has to have the

same amount -- it has to be made from a stock solution with five percent or less.

Sanofi said, well, "made from," that introduces a method step. If you have to say it's made from -- and this is a composition claim. So we amended it on the fly. I actually proposed it during the hearing. I don't know if you remember. And we said, okay, well, it is not meant to introduce a method step. It is meant to focus on the amount of ethanol in the perfusion and they have to have the same amount. So it got changed to the perfusion has to have the same amount of ethanol as the stock. You are worried about absolute amounts, how much you are delivering to the patients. Your Honor declined to accept the "up to two percent." Their arguments from their experts literally are saying the same thing in a different way. Their arguments against our claim construction and the one that Your Honor adopted are the same ones that they made during the Markman hearing.

Our position is that should not be allowed.

MR. SIPES: Your Honor, if I may respond briefly.

First of all, we agree that neither side should be rearguing claim construction through experts. We are on the same page there. That is not what this motion is about. In fact, our experts have come in with testimony about

application of your claim construction to the products at issue.

What this is about is attempting to revoke what they had acknowledged, what Your Honor had decided at claim construction, that they can't have a process limitation, that these are composition claims. So you didn't construe the claim they wanted as made from a stock solution. It has to be perfusion with the same amount of ethanol as a stock solution with five percent ethanol.

Our expert testimony goes to how much ethanol that is.

What is interesting is, they are actually speaking out of both sides of their mouth. Their experts for invalidity have come in with the very same amount of ethanol in the perfusion and say, yes, that's essentially free of ethanol. It turns out, that will scale, depending upon how much it says. You start with the stock solution, and you dilute it, it's not actually water, it's a perfusion, but it's mostly water. The upper limit is one milligram of your docetaxel, and you can go down from there to about .3 milligrams of the docetaxel as the minimum. You just can't have any more concentration because if you put it in the patient it causes severe harm. Perfusions have to be very dilute or you kill the patient, or at least it causes substantial harm. Apotex has shown what the upper limit is

on a perfusion based on a stock solution that is five percent.

What is interesting is he says, wait, we start with a stock solution that is more than five percent. We start with a stock a solution that is 23 percent. That is true. But what they do is they start with a smaller stock solution that is more concentrated. They dilute down more. I can write it down, so it will be clear. But I can walk through it.

What their experts have agreed and our experts have agreed is that, you know, a stock solution that you could use to make these perfusions essentially free is two milligrams per milliliter of docetaxel and five percent -- that would be stock solution that is essentially free -- dilute it down to one milligram per milliliter of docetaxel for the perfusion, and diluting it by half, it would then be two and a half percent ethanol.

We are all on the same page. Their experts have relied and had to argue why it might have been obvious to do that. We say it's not obvious. But we are all in agreement.

That perfusion at one milligram per milliliter, you will have ethanol at 2.5 percent. Of course, if you went more dilute, instead of one milligram per milliliter you went to half, you diluted it again by half, you have .25

percent. But that's the way "essentially free" works.

Based on the very concentrated stock solution, 10 milligrams per milliliter of the docetaxel, 23 percent ethanol, then they diluted not by half, by a factor of 10, so that with one milligram of per milliliter of docetaxel, they have 2.3 percent ethanol, less than what they agree is essentially free.

They would have exactly the same perfusion if in the course of diluting down the stock solution they stopped for a minute at two milligrams per milliliter of docetaxel, 2.3 percent ethanol, that would be their product. That would be their product, stopped at a stock solution that we would all agree, under five percent would be essentially free. Then you add more perfusion. You are down. That is what our experts show, is that as soon as you recognize this as a composition claim, as Your Honor ruled at claim construction, the ethanol they have in their perfusion is essentially free. They make it starting with a more concentrated stock solution. But the way they make their perfusion, we all agreed at the claim construction, doesn't affect the claim application. The claim is how much ethanol, what is the upper limit on ethanol that can be in a perfusion that is essentially free of ethanol?

Interestingly, all the experts have come up with the same number, which is 2.5 percent in the perfusion. Our

experts are applying that to their product. So their motion isn't designed to present and reargue claim construction. They are actually trying to change claim construction. They want to prevent us from having our experts put on testimony to apply the claim construction.

MR. HURST: Your Honor, the argument that you just heard from Mr. Sipes was very much the argument they made at the Markman hearing, where we spent a lot of time on this, and we had graphics up here to explain all the math that he just went through.

There is a correlation between stocks and perfusions. If the stock has too much ethanol in it, because it has more than five percent, that means it's not essentially free of ethanol, necessarily, the corresponding perfusion will.

That was the argument that we made at the Markman hearing, and that is what we understood to be the Markman ruling. Literally 60 percent of what Mr. Sipes just said he said at the Markman hearing itself. The same types of arguments.

So we feel like this issue has been resolved.

THE COURT: Apotex has the same issue.

MR. DRESNER: Yes, thank you. Actually, we have a similar motion. We support his position.

What Mr. Sipes is essentially arguing is that

there be an absolute limit on the amount of ethanol in the perfusion. Their experts say it's two and a half percent. That concept was rejected at the Markman hearing. And instead, what was adopted was an understanding that the amount of ethanol allowed in a perfusion has to be correlated to the amount of ethanol in the stock solution.

The products that are being accused of infringement, not some hypothetical stock solution or not some stock solution of the prior art that Mr. Sipes is talking about -- doing an analysis on validity is one thing. But when you are trying to establish an infringement of the product of the defendants, you have got to look at the defendants' products, the stock solution, and the perfusion related to it.

So I agree with Mr. Hurst that it has to be correlated with the stock solution and it has to be the same amount that comes from that stock solution.

Thank you, Your Honor.

MR. HURST: Your Honor, I would just echo what I just heard, so there is no need for me to respond at this point.

MR. SIPES: Your Honor, just to make it clear, this is really about summary judgment. It is no longer about claim construction. I think we are now on something -- all of our experts are applying the claim

construction in an effort to determine infringement. But as to the --

THE COURT: Counsel for Apotex responds in a very specific way.

MR. SIPES: And I want to take that up.

THE COURT: I think you should react to that.

MR. SIPES: It is clear that they really are asserting a process limitation. They are saying because the stock solution is over five percent, it cannot be the case that the perfusion is essentially free, which is a process limitation. That's exactly what was rejected at the claim construction. We are not looking for an absolute upper limit because, as we say, at each perfusion, depending on the concentration of the perfusion --

THE COURT: He talks in terms, I think properly so, of hypothetically.

MR. SIPES: But it's not hypothetical. In fact, what's remarkable to me is, I have always understood the law to be that the claims are construed and applied the same way for validity and infringement.

THE COURT: Yes.

MR. SIPES: That is something I learned from Patent Law 101. Each one of their experts has taken the position that for purposes of invalidity, the claim as Your Honor construed it reads on a perfusion that at one

milligram per milliliter docetaxel has 2.5 percent ethanol. Each of their products at one milligram per milliliter docetaxel has less ethanol, and they say we have too much ethanol for purposes of infringement, but for purposes of validity, that's essentially free. That strikes me as a process limitation.

Compositions claim compositions of matter. Our experts have been very faithful to that principle and Your Honor's claim construction. We have not gone back to the claim construction. We have applied the claim construction, which is what Your Honor said, what is the amount of ethanol in a perfusion that correlates to one made from a stock solution of five percent. All the experts for purposes of validity have achieved the same number, two and a half percent at one milligram per milliliter docetaxel, proportionally less as you dilute down. So we are all on the same page for validity.

They just want to construe the claim differently for infringement purposes. You can't do that. But, also, it's not faithful to what was the ruling at claim construction, which is, this has to be a composition claim. We are going to correlate it, but there is an amount of ethanol that is essentially free.

The experts can put on testimony to show what the upper limit is on a perfusion when your upper limit on a

stock solution is five percent. And the experts, at least for validity, have all agreed on what that is. That also applies on infringement.

We shouldn't be put in a position of having the claims narrowed for infringement purposes and broadened for validity purposes. There is a consistent number here. That is what our experts are doing.

MR. HURST: There is no inconsistency between our invalidity position and our infringement position. Our experts have taken the same position for both, frankly.

Judge, what Sanofi is asking right now is for you to divorce the correlation between a perfusion - a stock solution and a perfusion - absolutely divorce the correlation, which we understood was the core ruling at the Markman hearing.

This is Sanofi's position. You can start with a stock solution that has way too much ethanol in it. It has way too much ethanol. It can have 50 percent ethanol, according to Sanofi, and we would all agree it's not essentially free of ethanol because it's got too much ethanol. And suddenly you water it down enough, and you throw enough liquid in there, and suddenly the perfusion is essentially free of ethanol. And that really is completely divorced from the correlation between a stock and perfusion. You never change the amount of ethanol.

So if the stock solution has too much ethanol, the perfusion necessarily has too much ethanol. That was the core argument we made at Markman, and we did understand that to be Your Honor's ruling.

MR. DRESNER: Your Honor, I think Mr. Hurst expressed it well. I don't want to belabor the point. I think it is correct that Mr. Sipes is trying to divorce the perfusion that is made from the defendants' product.

THE COURT: What's your reaction to Mr. Sipes's point that it shouldn't be the case that we are looking at one position for purposes of invalidity and another for infringement?

MR. DRESNER: Certainly, I agree with that, Your Honor. The basis for validity is the same basis as it is for infringement. I referenced it in my earlier comments because he used a prior art reference that had five percent ethanol in it, suggesting that, well, that met the requirement of "free of ethanol." And he did the arithmetic to bring that down to a perfusion that had one milligram per milliliter of active ingredient, and showed, therefore, that the maximum amount of ethanol you can have in a perfusion is two and a half percent.

But that was something different from what we made or what Hospira makes.

Whether or not our perfusion meets the

requirement of free of ethanol has to be based upon the product we make and the product that we sell. And that has to be correlated to our stock solution, not to some prior art stock solution.

MR. SIPES: Your Honor, quickly. This will be made very clear at trial. But the question of infringement for perfusion has to be based on the properties of the perfusion, not the way the perfusion is made. It is true that if you start with a more concentrated stock solution, you can dilute more and end up essentially free. That is the logic of physics. The basic mathematics tell you, as you dilute, you make it more dilute. But there is a fixed correlation between stock solutions and perfusions.

We are all agreeing that from a composition of matter perspective, a perfusion at one milligram per milliliter docetaxel that has 2.5 percent ethanol is essentially free. They say, well, we can get around your claim by making it a different way. Even though we end up at exactly the same perfusion, because we make it a different way, we are not within your composition of matter claim.

That just can't be the law. That is what I thought was agreed at claim construction. But the Federal Circuit has been crystal-clear on this.

THE COURT: Let me give you the last word.

MR. HURST: Thank you, Your Honor.

They defined the limitation by percentage. Five percent is the way they defined it. That's the way they defined the limitation for the stock solution. They have to live with that.

That's the limitation.

So if it's got too much ethanol, however they have defined it, if it's got too much ethanol to start with in the stock solution, you are giving that amount of ethanol to the patient in the perfusion, so you can't have different answers. Either they are both essentially free or they both are not essentially free. And that's the correlation, Your Honor, that we argued at the Markman hearing, and that's the argument that we thought we prevailed upon.

THE COURT: What I want to do -- I am going to order this portion of the transcript -- I want to think about this. I will get back to you. It could be that I may grant your motion, without prejudice to certain things happening at trial. It may be that I am comfortable enough to do that, or that I am so uncomfortable that I want to hear more, and revisit the issue later on during the course of trial in realtime, as things crystallize better for me, or even later, during the submissions, proposed findings and conclusions, or even before that, perhaps, in the form of a motion to strike or whatever the case may be.

But there are going to be a number of opportunities for me, it seems to me, to visit this issue. But I want to first do it with a little more opportunity to reflect back on the order and these arguments that were made.

I am going to reserve on both Hospira's motion that is filed at Docket Item 269 and Apotex has the same --

MR. SIPES: Your Honor, I believe it's Apotex's Motion in Limine No. 5.

THE COURT: 268, okay, and 269.

I have reserved on 268 and 269.

All right. Mr. Hurst --

MR. HURST: A second motion.

THE COURT: Which one?

MR. HURST: Motion No. 2. It's perfusion. For the other three, we would be happy to rely on the briefs, Your Honor.

THE COURT: 272. Okay.

MR. HURST: Thank you, Your Honor.

This also relates to a claim construction issue, but it arises in a different way. It was not one of your Markman rulings, Your Honor. It was an agreement between the parties where we have since parted ways.

The word is perfusion. And the purpose of this motion is that right now, in our view, Sanofi is through

expert reports trying to construe that word perfusion with sort of a detailed multi-layered definition that implies a series of additional requirements relating to toxicity, effectiveness, stability, all of which, if they wanted to add those limitations, in our view, the time to do it was at the Markman stage, not through expert reports later on, because it's literally an argument about the meaning of the word perfusion. I guess my first position is, it's too late for that. If you wanted to add those requirements, you should have done it at the Markman stage.

And the agreed definition is what is, according to Sanofi, adding all these limitations, the agreed definition was as simple as, a perfusion is a diluted stock solution -- that's all it is -- suitable for administration to patients.

"Suitable for administration to patients." That's what we agreed to -- "and suitable for infusion to a patient." I am sorry about that. I said "for administration." It's "suitable for infusion to patients."

Sanofi's argument is, well, to be suitable for infusion to patients, it's got to be nontoxic, it's got to be sufficiently effective, it's got to be stable enough.

Those three words, suitable for infusion to patients, do not, at least to us, imply toxicity levels, stability levels, effectiveness levels.

We happen to have a case that is literally on point. It was from Judge Shadur in Chicago. And he was construing the words "suitable for oral administration." It is a very similar phrase. We agreed to "suitable for infusion," honestly, Judge, never intending to imply toxicity, stability, in fact, none of that. Just: Can you give to a patient? Period.

Judge Shadur, in that case the argument was this: "suitable for oral administration," the other side argued to be suitable for oral administration, it's got to be nontoxic, it's got to be stable, it's got to taste good, it's got to be effective. Exactly the same arguments. Judge Shadur said that that simple phrase to any objective reader, his phrase, "to any objective reader," does not imply all these additional requirements to the phrase.

The point that he made is the point that applies here. A medicine doesn't have to taste good. Everyone understands that. Medicines can taste bad. It might be a bad-tasting drug, but that doesn't mean it's not suitable for oral administration.

The same point here. A perfusion, Judge, all it is is a pharmaceutical that is designed to give to patients. You know what? We all understand perfusions. They don't necessarily have to be stable. They can be unstable. And that is a problem with a perfusion. It doesn't make it not

a perfusion. That perfusion might not be effective. When you give it to patients it might not work. But that doesn't make it not a perfusion.

It might be too toxic. That has happened, in fact. Perfusions have been taken out of the marketplace, and because they were so darned toxic, they literally started to kill people, they were taken off the market. But that doesn't make it not a perfusion.

Our position is, number one, it's too late to add a bunch of extra meanings to the word perfusion, and, number two, even if it's not too late and you were to entertain this argument, we think it ought to be rejected because the word perfusion doesn't imply all these really indefinite limitations relating to undefined stability, toxicity, and effectiveness levels.

Thank you, Your Honor.

THE COURT: Thank you, counsel.

MR. SIPES: Your Honor, if I could respond.

The parties agreed, this is what they agreed to at claim construction, rather than submitting for claim construction. It said perfusion means a solution suitable for infusion into patients. That is the agreement. That is the claim meaning, we have all agreed, all the parties, to be applied here. "Suitable for infusion into patients." As their own papers show, they put in this NCI Dictionary,

perfusion is equivalent to intravenous infusion.

We are not talking about taste, Your Honor. We talking about formulating a drug to be infused into your bloodstream for purposes of chemotherapy. The question is, what is meaning of the phrase "suitable for infusion into patients"?

THE COURT: Why did the agreement break down? What happened?

MR. SIPES: Only for purposes of validity, they have come in and said if the prior art would have killed the patient, it still anticipates or renders obvious. If the prior art would have been so toxic that you couldn't administer it to patients, it still renders the claims obvious or anticipated.

THE COURT: You are saying that can't be a perfusion.

MR. SIPES: The challenge in creating this invention -- they want to say the challenge is getting it out of the needle, making it liquid. The challenge of making the infusion -- I don't know about oral products. I have questions about oral products. I don't want to take an oral product that kills me. But I will take medication that tastes bad. But I'm not going to have infusion in my bloodstream of medication that it's going to kill me, that's going to have such adverse effects that I --

THE COURT: You are saying that is not suitable for infusion into patients.

MR. SIPES: There is even difficulty with intravenous infusions getting the medication to be in solution to actually get to the tumor. There are infusions that aren't effective.

THE COURT: Hold on.

Mr. Hurst, I heard what you said when you talked about infusions that have been put on the market that kill people. But that can't be a good, a desirable result.

MR. HURST: It's not.

THE COURT: With hindsight, you would say, wouldn't you, that those infusions were not suitable?

MR. HURST: I would say yes, they were perfusions, though, Your Honor. They were certainly perfusions. And that's the word in the claim.

THE COURT: If you label something -- if you say something, a perfusion, by definition, is suitable for infusion, for induction into the human body, aren't you saying that it won't kill them, inherently?

MR. HURST: I am certainly saying that it won't kill them, Your Honor. But I wouldn't say that it's not toxic.

THE COURT: That may be. All I am saying is, your reasoning seems to be a little circular to me. That is

my point.

I cut you off.

MR. SIPES: Our point is, all we have our experts doing is offering opinion testimony on what it means to be suitable for infusion into patients. It seems to us that is fair testimony on the agreed claim construction.

If they want to come in with their experts and say, that is a suitable infusion even if we gave it to patients and it killed the patient, I suppose that's their right, to apply the claim construction suitable for infusion to patients. I don't find it very convincing if I go to the doctor and say, I don't want a medicine that is suitable for infusion into me. I am expecting the doctor to administer something to me that is therapeutically acceptable. Not something that is not.

THE COURT: Here is my feeling. I would rather not have an additional claim construction issue deal with. If I do, I do. It seems to me that this is something that reasonable minds could agree upon. And you did. I'm still a little at sea as to why you are now not agreed.

MR. HURST: Let me give you a more concrete example.

Clearly, a perfusion is designed to give to patients.

Two things, just two examples. Absolutely,

positively, perfusions can be toxic. No doubt about it. Cancer drugs, in fact, are designed to be toxic. So the argument that Sanofi's experts are now making is, well, the prior art doesn't meet it because who knows how toxic this would have been. Obviously, it was designed for patients, but who knows how toxic it would have been.

Our point is, that is not a limitation in the claims. Everybody understands that pharmaceuticals can be toxic. In fact, cancer drugs are designed to be toxic.

Another example. Stability, Your Honor. Stability. There is a prior art reference where the perfusions lasted two hours. And Sanofi's experts are saying, well, that is not a perfusion, it's got to last for four hours, because the word perfusion implies that it's got to last X amount of time.

THE COURT: That is an additional limitation that is not commonly understood.

MR. HURST: The point is, we certainly never agreed to these fine limitations. That is my point. All this extra baggage is really a claim construction issue that nobody ever agreed to.

MR. SIPES: Let me put that in context, because it's interesting he raises those. We can talk, for example, about one piece of prior art that has already come up, one of the Tarr references, which is a formulation of a

taxane -- this is really a case about taxanes, it is a particular class of compounds -- where it was a very distinguished researcher, Dr. Yalkowsky, who was attempting to come up with a new formulation for paclitaxel because the existing formulation had killed the patient from anaphylaxis. That was one thing we saw, a problem with anaphylaxis.

He tried a very exotic surfactant. Among other things, he found it didn't have sufficient stability. It was only two hours. He wrote, this is not suitable for use in an IV bath. The art knows when it's suitable, because if it doesn't stay in solution, it crystallizes out, then you can't get it into the patient or it crystallizes in the blood stream and it is not delivered to the tumor and it causes nephritis or phlebitis, terrible problems. It is all about suitability.

This is not something we are reading in. The patent claim itself talks about the need for physical stability, for keeping it in solution. That was one of the problems. That was in the art. People know, formulators know what it means to be suitable for infusion into patients.

That phrase, which we both agreed to, is not a vague phrase. It's understood. We have our experts talking about what is suitable. The prosecution history of the

patent talks about what is suitable.

They are taking a reading of suitability -- I hear their point that with cancer drugs you accept a certain level of side effects. Granted. But you accept a certain level of them. You don't accept where they precipitate out and you get no therapy and just phlebitis or nephritis. You don't accept toxic shock.

The other thing about that pluronic L64, the Tarr reference, the amount that pluronic used was above the LD50 but it killed half the patients. Those things you don't accept. In fact, Dr. Yalkowsky wrote a subsequent article where he said, we have been trying to reformulate taxanes for almost ten years and they have all failed, and one reason they failed is not enough stability, and another is too much toxicity. This was the problem to be solved.

THE COURT: So there is not an understanding out there among persons of skill as to the meaning of suitability? There is not agreement in the art?

MR. SIPES: We believe there is. And our experts have put in a lot of testimony about what it means to be suitable for infusion into patients.

There are cases. This came up in the District of Delaware, I believe it was Judge Jordan who may have had a case, again, with an injectable, where they construed "physically acceptable" to be suitable for, you know,

injection to patients, where it was, you know, a non-pyrogenic, that is, causing fevers, causing side effects. "Otherwise suitable for administration into patients," it appeared there was agreement over what that meant. We thought there was agreement.

When we agreed with them, we thought we all were on the same page, what was suitable for infusion into patients.

It is not that they have come in with prior art, which even the prior art says is unsuitable. They are saying, that is suitable because we understand suitable not to include the effects on the patient.

THE COURT: So, then, my question to both of you is, what is your understanding of persons of skill in the art, persons who have skill in this particular field, what is their understanding of what suitable means?

MR. SIPES: My understanding --

THE COURT: Not what a lawyer wants to argue to me. Do we agree? Is there agreement out there in the world?

MR. SIPES: My understanding from our experts -- I expect you will hear differently from the other side -- is that when a formulator is making a perfusion to be suitable for infusion into patients for intravenous administration, there is an understanding of a minimum time in which it has

to stay in solution so it doesn't crystallize out. There is an understanding about the level of toxicity. Actually, we have an expert toxicologist, toxicologists consult with formulators when they are trying to formulate --

THE COURT: When you say a level of toxicity, how is that defined?

MR. SIPES: It is actually defined beginning with animal tests. I don't want to get into too much detail.

THE COURT: I don't, either. Can we agree it's at least not toxic enough to kill people?

MR. SIPES: In fact, there is a term that is called the highest non-lethal dose. That is a standard toxicology term. And I will say you got to be one-third of that. We have an expert toxicologist, Dr. Rodricks, this is what he did for a living.

THE COURT: I get that. I am trying to get you to tell me what you understand as a lawyer.

MR. SIPES: That is our understanding, that there are principles of toxicology, principles of physical stability, of sterility, that are understood in the art, that are defined.

THE COURT: So we need a non-lethal dose. We need a certain degree of stability so it doesn't diffuse and can be stable enough to render some effect.

MR. SIPES: Correct, sterile, sterility, and things that like. We don't inject things into patients that are not sterile.

THE COURT: What else?

MR. SIPES: It has to be non-pyrogenic. In the area of highly insoluble cancer drugs, you have to have distal tumor activity, you have to keep it in solution so that it will not precipitate out at the site of the injection, but will actually --

THE COURT: Be delivered throughout the body.

MR. SIPES: To put it in more general terms, it has to deliver the drug in an effective way.

THE COURT: Okay. Four elements.

MR. HURST: Did you include effectiveness?

THE COURT: He said effectiveness.

MR. HURST: Those four limitations that are being sought to add to Claim 5, remember, the word is perfusion, they are nowhere in the claims, nowhere at all. And honestly, Your Honor, a person of ordinary skill in the art would never add all of that to the simple term "perfusion."

THE COURT: What would the person of ordinary skill, Mr. Hurst, understand perfusion to mean?

MR. HURST: Simply something that is designed to be a pharmaceutical to be infused into a patient. It is

that simple.

Moreover, just to make it pretty clear, look, it's suitable for infusion before you test it in a human being, because, remember, you can infuse it in the patient to test it before you know how toxic it is.

THE COURT: Say that again. It's suitable before injection?

MR. HURST: Yes.

THE COURT: Even if you know it will kill the patient?

MR. HURST: It wouldn't be a pharmaceutical if you know it would kill the patient.

THE COURT: So you accept "non-lethal dose."

MR. HURST: I accept "non-lethal dose." The intent has to be suitable to treat a patient.

THE COURT: Do you accept stability? If the intent is to treat a patient, must it not be stable enough to be effective? You asked whether you include effective.

MR. HURST: No, Your Honor, I wouldn't.

THE COURT: So we are giving placebos.

MR. HURST: A perfusion can be a placebo, sure. A perfusion is simply something that you infuse into a patient. Think about the realities of what happens out in the pharmaceutical world. You create a perfusion in the lab. You have got your stock solution, your concentrate,

you put it in the perfusion bag. Right now you have never tested this drug in a human being.

Is it suitable to infuse into a human being? Well, you know, you hope it is going to be fine, you hope that it is going to be effective. You inject it into a human being, it has no effectiveness at all. It turns out your drug is a complete failure. Does that mean you didn't give them a perfusion? Of course, not. You gave them a perfusion. It just didn't work.

I'll give another example. You have a stock concentration. You turn it into a perfusion and put it into an IV bag, and gosh darn it, it only lasts for a half-hour. Was it not a perfusion for a half-hour? Of course, it was a perfusion. It just didn't turn out to be a very good commercially useful one.

As another example, you have your stock solution. You create yourself a perfusion. You deliver it to patients in the hope that it's not going to be toxic. Gosh darn it, everybody you give it to loses all their hair. Does that mean you didn't give them a perfusion? No. You gave them a perfusion. It turned out to be a terrible one. But it's still a perfusion.

THE COURT: So your experts would say a perfusion is?

MR. HURST: Designed to be infused into patients

as a pharmaceutical. Simple as that. No extra baggage relating to undefined toxicity levels. No extra baggage relating to how effective it has to be. No extra baggage relating to how stable it has to be.

Those four arguments should have been made at the Markman stage if we were going to be adding all of these limitation to a claim.

THE COURT: I agree with that.

MR. HURST: I commend Judge Shadur's opinion in the Medeva case.

THE COURT: I agree with your general premise, and I want to get counsel to react to the examples you have just used and the logic inherent in those citations.

MR. SIPES: I want to take both that and the case law, if I could.

First, I don't know what he means by, now he is saying it could be infused in a patient as a pharmaceutical, because that seems to me is achieved. The language that we all agreed on -- I resent this argument that he said we should have raised this at claim construction. We agreed to "suitable for infusion into patients." We have an understanding about suitability. But even if he is saying it has to be a pharmaceutical, well, I know what a pharmaceutical is.

THE COURT: I think he just added that during

his most recent comment. That wasn't the definition you offered earlier. You said a perfusion is a diluted stock -- I am paraphrasing -- stock solution suitable for infusion into a patient.

MR. HURST: That is fine. The question we have is: What does it mean, suitable for infusion? I am saying it doesn't include all those extra things. It's just designed to be a pharmaceutical --

THE COURT: I thought I understood you to say that would be an acceptable definition of the word perfusion.

MR. HURST: Yes, as long as we didn't have the word suitable, including toxicity and --

THE COURT: Just what I just said. That's his position.

MR. SIPES: Perfusion we are talking about here, it is a pharmaceutical composition. That is a therapeutic composition which could then be safe and effective. That is what suitable for infusion --

THE COURT: There is where you part ways. I don't know how you ever agreed.

MR. SIPES: I think we have the better of the argument, because even their own prior art, when they talk about suitability for infusion into patients --

THE COURT: You may have the better argument.

But this may be one of those rare times that I am willing to hear extrinsic evidence on the meaning of a term in order to help me do the claim construction.

MR. SIPES: We believe the way to do it -- our experts have testified about what it means in the art to be suitable for infusion into patients.

Your Honor, they keep citing this one case, the Medeva case, which was an oral case. I think it's questionable even on its facts. But it was in an oral product.

THE COURT: It's questionable as to whether a judge's construction of a term in an entirely different context -- it has no precedential value in that regard, and you know that.

MR. SIPES: The Court relied on the wide range of things that people will take orally.

THE COURT: Here is what I am going to do: I will do this construction in realtime. It's a term that the parties should have identified early, quite frankly. It would have been helpful to have the Court have the opportunity to not have this issue to wrestle with. But it's there.

MR. SIPES: I apologize, Your Honor. We thought when we had "suitable for infusion" that that encompasses that it was safe and effective to give to patients.

THE COURT: I have got your claim construction briefs. And that's the way I will treat these briefs in support of your various positions on this particular issue.

Did Apotex weigh in on this one as well?

MR. DRESNER: We did not, Your Honor.

MR. HURST: Your Honor --

MR. SIPES: I wanted to respond to the case law.

There are a couple of cases on injectables, on drugs that are actually injected or infused into patients. There is the Pharmacia case from 2006, that is 447 F.Supp. 2d. 363. This is in our papers. We cited to it. That was dealing with one that is injected. The parties there agreed that the term there, that it would be intravenously injectable, sterility, pyrogenicity, things that are, the Court said, sterile, pyrogen-free, and suitable for administration to humans and animals. Clearly, the Court was saying that these aspects of the biological response are important and that "suitable for administration to humans" is a meaningful term, a meaningful requirement of these injectable products. In that case, the Court rejected stability because it said the patent there didn't talk about stability. In our case the patent talks about stability.

THE COURT: There you go. So much for precedent.

MR. SIPES: In the Amgen case, where the

Court --

THE COURT: Counsel...

MR. HURST: Can I ask for a clarification?

THE COURT: Yes.

MR. HURST: We, obviously, had no meeting of the minds when we reached this agreement, as you can tell. As I understand it, we will go to trial and we will have live claim construction on the word perfusion.

THE COURT: Yes, that's exactly what's going to happen.

MR. HURST: Thank you, Your Honor.

THE COURT: So this motion is, obviously, taken under advisement. Judgment is reserved.

MR. HURST: Thank you.

THE COURT: Mr. Hurst, you are prepared to stand on your papers with regard to the other motions?

MR. HURST: Yes, I am, Your Honor.

THE COURT: That leaves us with Apotex having some additional motions.

MR. PAPPAS: Your Honor, if I may.

With respect to Hospira's motion to preclude evidence regarding secondary considerations, I understand Mr. Hurst is saying he rests on his papers.

THE COURT: That's what he is saying.

MR. PAPPAS: I understand. Your Honor --

THE COURT: You want to argue?

MR. PAPPAS: I would like to be brief, because I think we can dispose of this. And I also want to give Your Honor, if you have a chance, if you want to ask any questions, we are here, I would like to be able to respond.

THE COURT: Let me find the motion first, Mr. Pappas.

MR. PAPPAS: Very well.

270?

MR. PAPPAS: I think so.

THE COURT: Go ahead, Mr. Pappas.

MR. PAPPAS: Your Honor, like I said, I think this can be disposed --

THE COURT: Here is the note that I made to myself, for both of your benefit. I said: Seems plaintiff is right. This is a weight issue and is possibly MSJ, motion for summary judgment. That's the note I made to myself.

MR. PAPPAS: That is exactly what it amounts to, Your Honor. What I would simply say is, both --

THE COURT: That means, if he is relying on his papers, you have already won, potentially.

MR. PAPPAS: I just want to say that both Hospira and Apotex, basically what they are advocating you do, in a case in which they have attacked two United States

patents as obvious, is disregard the entire body of Federal Circuit precedent, which says that if evidence is proffered by the patent holder, objective indicia or secondary indicia, it must be considered.

And that's what we have to say.

But the upshot of their motion is, they want you to conclude that there is nothing novel, nothing inventive, and whatever was done was obvious, and therefore, from there, Mr. Hurst says, therefore, Judge, you don't have to hear any of the secondary indicia.

That is why we think it can be disposed of.

THE COURT: I think you are swimming downstream on this one. We will leave it there.

MR. PAPPAS: Thank you.

THE COURT: Apotex has a motion with regard to Dr. Kaler. Is that still extant?

MR. DRESNER: Yes, Your Honor. But, Your Honor, I took your comments at the outset of this hearing to heart. What I would like to suggest is that, we have four remaining matters. One of them has already been dealt with in connection with one of Hospira's motions. We would like to present and argue one of them, which Mr. Hurst alluded to earlier, which is a big time issue, that is the bioequivalence matter.

The other three motions, Your Honor, deal with

requests to preclude testimony from specific expert witnesses. We believe Your Honor can deal with that on the papers or certainly on the fly.

THE COURT: On the fly, yes. That's consistent with the notes that I have made to myself here.

MR. DRESNER: Okay, Your Honor. We would like to present the bioequivalence one.

There is one issue in a footnote in the Dr. Kaler motion that also appears in the body of the proposed pretrial order that I would like to address after we address the bioequivalence matter.

THE COURT: I have bioequivalence. That is 267.

MR. DRESNER: Mr. McTigue will present that, if that's okay.

THE COURT: Mr. McTigue.

MR. McTIGUE: Thank you, Your Honor.

So, Your Honor, that would be Apotex's Motion in Limine 4.

THE COURT: Yes. And it's docketed at 267.

MR. McTIGUE: Your Honor, Apotex is moving to exclude evidence of bioequivalence not because there is any issue between the parties over whether or not Apotex's product is bioequivalent. That's not the issue for the Court to decide.

Bioequivalence is, in essence, an analysis of

the drug, in this case the active ingredient docetaxel, into the patient's bloodstream.

What you have in front of you, though, Your Honor, importantly, no claims at issue make reference to any biological effect, much less the rate or the extent that the API becomes available in the patient's bloodstream.

So, taking to heart what Your Honor was saying about judicial efficiency, what we are trying to do is say, bioequivalence is a red herring. That is not something that the Court has to decide.

We are actually not even here under an ANDA, Your Honor. This is a (b)(2).

So the fact that Apotex's product is a free-solvent system, and the fact that Apotex's stock solution substitutes PEG 300 for polysorbate 80, we are under a (b)(2), not an ANDA, but we are not arguing that somehow Apotex's product isn't bioequivalent. We are saying bioequivalence by itself isn't essential and it isn't something the Court has to decide.

However, Your Honor, taking the basic and novel properties issue straight on, the plaintiffs have said there is three basic and novel properties. Now, there is going to be discussion, Your Honor, at the trial about whether or not there are more. And we believe that the basic and novel properties issue is actually more expansive than how

plaintiffs' position BNP.

But their own three basic and novel properties, Your Honor, the first one is the ability to increase the concentration of the API in a perfusion. That has nothing to do with bioequivalence at all. Bioequivalence, again, has nothing to do with perfusions. It's the API in this case in the bloodstream.

Their second is the ability to create a perfusion at a concentration that is physically stable. We have been talking about physical stability today, Your Honor. But physical stability has nothing to do with bioequivalence.

And the third basic and novel property that they espouse is it can be administered with reasonable expectations of avoiding anaphylactic or alcohol intoxication manifestation.

Again, Your Honor, whether or not there is a side effect profile to this has nothing to do with a determination on bioequivalence. So to streamline the case, Your Honor, Dr. Kaler's report discusses bioequivalence as one way that they try to get to an infringement position that doesn't match their basic and novel properties and is not at issue in this case.

MR. SIPES: Your Honor, if I may.

What we are going to hear, in asserting

bioequivalence, what they need to deal with in terms of testing, in terms of representation to FDA, is the additional ingredient, excipient, in their products, which is PEG 300. Because this is a perfusion, that is, an intravenous infusion, the FDA war is not just about the active ingredient, but the biological effect in every excipient, and the effects even in the perfusion, because it's all administered in the bloodstream. It's technically called, everything is, it's biologically available. It makes sense.

There are many issues that they are asserting in defense to infringement about the effect of PEG 300 that are addressed in their testing for FDA. Let me give you one example: viscosity. Their experts have said that PEG 300 has a material effect on their perfusion because it changes the viscosity. PEG 300 is more viscous.

They are right that viscosity is an important issue with the perfusion. If it doesn't distribute through your bloodstream and it clumps in one part, it's not effectively distributed throughout. They are right, viscosity is important. For that reason, it is asserting bioequivalence, they studied the viscosity of their product and showed that, in fact, the presence of PEG 300 isn't affecting the viscosity of the perfusion in the perfusion or when administered.

There are a lot of properties like that. Actually, Hospira hired an expert in the area of surfactants with taxane, a fellow named Dr. Alex Sparreboom, who is now down in Memphis. He supervised tests involving adding the PEG 300, adding the citric acid, which is another excipient that Hospira uses, to look, what are the effects of each of these additional excipients on the properties of the perfusion, in the perfusion then as administered.

We are relying on all that testing and all of those representations about the results of those tests to FDA to show exactly what they showed FDA: that these excipients don't affect the properties of the perfusion; to show that, therefore, it doesn't have the material effect on the properties. But we are doing it on a factual basis. It is not we are simply saying because they are bioequivalent they infringe. We are saying, the inquiry for Claims 2 and 10 of the '562 patent, those are the two claims that contain "consisting essentially of," requires an analysis of what effect are the unlisted ingredients, the PEG 300 in one case, the PEG 300 and the citric acid in the other, on the properties of the perfusion. The testing that was done for FDA is addressed to that question, because FDA wants to know exactly the same answer: What is the effect of those additional excipients on your product? That is what we are doing. That's what Dr. Kaler does.

THE COURT: Mr. McTigue.

MR. McTIGUE: Your Honor, first, I have four small children, so I apologize for the boisterous voice I am trying to talk over sometimes.

What he essentially said was the FDA has the same concern. That is the problem, Your Honor. What the FDA is comparing is bioequivalence of the commercial products. And what the Court said, actually, the Federal Circuit in AquaTex -- and it's in our briefs -- is it's erroneous, because infringement, either literally or under the doctrine of equivalents, does not arise by comparing the accused product with a commercialized embodiment of the patentee.

What we are talking about is the effects -- and I agree with him that there is more than his three basic and novel properties. He mentioned one.

THE COURT: You are saying this is all beside the point.

MR. McTIGUE: That is exactly right, Your Honor, because what we want to focus on is those claims. Again, I will reiterate: None of the claims deal with bioequivalence.

THE COURT: If that is the case -- and I think he is right insofar as his assertion with regard to whether the claims deal with bioequivalence, my recollection

vaguely -- what are we talking about here? His point is, it's hornbook patent law as to how you prove infringement.

MR. SIPES: If we are talking about the fact of bioequivalence, there is only one claim element, which I don't believe they have challenged because their experts have relied on it, too, where bioequivalence analysis matches the requirements of capable of being injected without anaphylaxis, where the properties of their product, the rate of anaphylaxis is determined by the fact that it's bioequivalent to an existing product. And we know the rate of anaphylaxis for that product. Their experts have relied on that, too. Their experts have said the same thing, that because the two products are the same, we can tell the properties of the accused product in terms of anaphylaxis from the testing there.

So on that one, that claim element goes to the physiological effects of the accused product. And that is specifically dependent upon bioequivalence. I think there, that's one where bioequivalence matters. For the rest of it, it's not bioequivalence we are relying on. We are relying on the testing done by the defendants of each of their excipients that was submitted to FDA with their assertion of bioequivalence. But it's the testing itself of the effects of each of those excipients. That is clearly proper under the case law, because it is going to the

question of the effect of each of these unlisted ingredients on the product.

THE COURT: Mr. McTigue, do you want to react to that?

MR. McTIGUE: Your Honor, I go back to the fact that this isn't a case where the parties are arguing over the biological effect, much less the rate or the extent to which the API is delivered into the body. None of the claims --

THE COURT: You are talking about composition.

MR. McTIGUE: We are talking about composition, Your Honor. If counsel wants to talk about viscosity or some of the other evidence that is out there, that is test evidence, that is in addition to what their three basic and novel properties are, we will have that discussion at trial. But what we don't want is somehow -- and we do not subscribe that somehow if you equate bioequivalence, all of a sudden, that relates to the claims. And that's the important part. It doesn't impact anything that's at issue for the Court, which is the claim construction.

THE COURT: I agree with that, that proposition, that assertion.

MR. SIPES: I am not sure we disagree. It's not the fact of bioequivalence. It's the testing, the underlying testing.

THE COURT: As counsel just argued, we can deal with that at trial.

I think I understood you to say that.

MR. McTIGUE: Yes.

THE COURT: So I am not sure how -- I think I will grant the motion. I think we all understand, given the discussion we have just had, what that grant intends. I will grant it as framed.

MR. SIPES: Your Honor, so I can be clear.

THE COURT: You can introduce evidence of testing.

MR. SIPES: Excellent. In terms of the rate of anaphylaxis of their product, I assume we have agreement that we can rely on their assertion to FDA about the physiological effects of their product.

THE COURT: To the extent -- yes. To the extent that we all understand what we are doing, and that is not comparing one commercial embodiment to an accused composition, I think we will be fine. And that still leaves the opportunity to object in real time where that line is crossed, in your view.

MR. McTIGUE: Thank you, Your Honor.

THE COURT: So the motion is granted.

MR. HURST: Your Honor, one of the three motions I relied on in the papers was a mirror-image of that. It

was a mirror-image of Apotex's.

THE COURT: Let's identify that now.

It's docketed 273. That's granted as well.

Counsel for both defendants are going to stand on their papers with regard to 264 -- this is Apotex -- their No. 1 and their No. 2, which is at 265, and their No. 3, which is at 266.

MR. DRESNER: That's correct, Your Honor. I had pointed out, there is one matter, in the Kaler motion, which is No. 1, it is a footnote. It is not to the heart of the motion. But there is a footnote in that motion that tracks a comment that was added to the draft of the pretrial order that I think needs to be clarified.

THE COURT: Let me get that out. Where is the footnote?

MR. DRESNER: The footnote appears in the Sanofi response to Apotex Motion No. 1.

THE COURT: What page?

MR. DRESNER: Page 4 of the response, Your Honor. It raises an issue regarding Your Honor's claim construction of the expression "consisting essentially of." You may recall that in Your Honor's order, the term "consisting essentially of" was a disputed term. And Your Honor ruled that the term "consisting essentially of" in Claims 2, 5, and 10 of the '561 patent means such-and-such.

Whatever it is, we don't dispute.

The issue is whether or not the term "consisting essentially of" applies to all three of the claims that Your Honor said it does. Sanofi says, no, that was a typographical error, it was an error here and the Judge did not mean to include it in Claim 5.

It's been five months since this order was issued. Experts on both sides, frankly, have looked at that expression, both in Claim 5 and not in Claim 5. Some of the experts have taken the view that it doesn't appear in Claim 5, and the reason is that Your Honor also construed another expression that appears in Claim 5, the expression "which includes." And you concluded that that means comprising.

And, therefore, there has been some confusion, if you will, as to whether Claim 5 is an independent claim or a dependent claim. If it is a dependent claim, then it should include the "consisting essentially of" language, just like Claims 2 and 10.

By the way, none of the three claims, 2, 5, or 10, actually contain those words. They appear there by virtue of the fact that all of those claims do refer back in some way or another to Claim 1, which has those words in it.

One of our experts, during his deposition testimony, raised the issue as to whether or not Claim 5 really is a dependent claim. Another of our experts has

given an opinion based on it being an independent and a non-independent claim.

We take the position that Your Honor meant what you said and that Claims 2, 5, and 10 include that expression. Sanofi believes that it doesn't.

THE COURT: Okay.

MR. PAPPAS: Your Honor, first, I think it always helps to turn to the original document in a situation like this.

I really don't need to quote Judge Sleet to Judge Sleet. But what you said was, you were very clear, that's why the only explanation we have is the sentence about 2, 5, and 10 may have been inadvertent, because Your Honor was very clear, in Paragraph 3, you said, "The term 'which contains'" -- that is the language the parties hotly disputed in Claim 5, you wrote an entire paragraph: "The term 'which contains' in Claim 5 of the '561 patent is construed to mean 'comprising.'"

Not "consisting essentially of." You said: "comprising."

Indeed, you had Footnote 8. Footnote 8:

"The Court rejects Hospira's proposed construction."

What was Hospira's proposed construction? Just what counsel for Apotex said: that which contains is

open-ended, synonymous with comprising or including, and does not exclude additional unnamed ingredients.

You rejected that.

Now, let me tell you what else.

At the Markman hearing, this argument that counsel has just made, that Claim 5 is really dependent, not independent, was waived.

I quote to you from the transcript, Page 116, where Mr. Sipes said, quote -- this was when he was debating Mr. Hurst's point about Hospira thought the prosecution history meant that it should not be "which contains," and you rejected that. Mr. Sipes said, "I would point out as well that this also makes clear that Claim 5 is an independent claim."

I am reading this, Your Honor, because this took place at the Markman hearing.

"But the language of Claim 5," Mr. Sipes said, "makes that clear, too. I don't think you will find it in their briefs, any argument that Claim 5 is dependent. That is new to this area."

The argument counsel for Apotex just made was never in their Markman briefs. In fact, Mr. Sipes took it on to make sure it was clear, and said, "There is no argument about it being dependent. It was argued at the hearing, but it wasn't in their briefs."

The Court's response: "I don't think that is an issue."

Off the table.

So, Your Honor, we believe you couldn't have been clearer about what "which contains" means in Claim 5, and that it can't mean "consisting essentially of," because, of course, Claims 2 and 10 do refer back and use the words "consisting essentially of," whereas Claim 5 says, "contains."

That was a very disputed topic.

So our point is simply this: That issue has been waived, and second, Your Honor, we think that's an explanation of your claim construction ruling that makes sense.

Then as an alternative argument, Your Honor, Claim 5 flunks both tests of whether or not it could ever be construed to be a dependent claim. First of all, Claim 5 refers only to the compound in Claim 1, not the entire Claim 1. And it's not a composition. And Claim 5 does not further limit Claim 1 because Claim 1 is drawn to two different types of compositions, a stock solution and a perfusion. And Claim 5 is a perfusion.

Your Honor, under any stretch of the imagination, we submit you meant what you said in your claim construction ruling.

The reason we brought it up in the pretrial order, Your Honor, is because we have been schooled, by my own presence in your Court and by local counsel, that you do not take kindly to attempts to reargue claim construction, which we believe Apotex is trying to do. And when we saw this in one of their experts' reports, that's why we brought it up in the pretrial order, because if at all possible we would like to leave here today with our understanding that Claim 5 is as you addressed it in Paragraph 3 of your order.

THE COURT: I think Mr. Pappas has correctly -- I will commit to this: I will go back and reexamine this issue. But I think the footnote correctly sets out the Court's view. I generally do understand the difference between "comprising" and "consisting of." And when I go to that -- I am usually very terse in my orders, as you know, probably much to the annoyance of my colleagues upstairs. But they haven't told me to stop it. So I at least give a quickie footnote to you from time to time. In this case I did. That indicates to me, though I don't have perfect recollection, obviously, of exactly what happened, I think that helps refresh my recollection as to what it meant. I think I meant what I said.

MR. DRESNER: Your Honor, just a final point. Whether Claim 5 is independent or dependent is really beside the point. I don't mean to argue that too extensively.

THE COURT: Not "too extensively."

MR. DRESNER: The point I do want to argue is whether or not Your Honor meant that, consistent with what Your Honor said in the order, that Claim 5, like Claims 2 and 10, includes the expression "consisting essentially of."

The phrase that Mr. Pappas referred to that Your Honor construed, "which contains," is a phrase -- you correctly construed that to mean "comprising." But that is a phrase that occurs in the claim after the claim refers back to Claim 1.

THE COURT: Keep in mind -- I am going to cut you off, because keeping in mind Mr. Pappas's I think well-taken point with regard to waiver, I am not going to hear you further on this, but I will go back, even in spite of the fact that I think he is right on waiver, I will go back and look at it. I don't think you should anticipate any change in my view. If there is, I will issue a short order. Then you can jump on me at trial, but not until then. I think things would stand as they are today.

MR. DRESNER: Thank you.

THE COURT: All right. I think we know what you need to hear from me on. I think we have gone over that.

MR. DRESNER: Your Honor, can I raise a housekeeping matter?

THE COURT: Hold on. Again, to recapitulate,

you need to hear from me on the footnote matter, if I am going to change anything, on Apotex's Motion No. 2, and Motions 2 and 3, and Hospira's 4 and 5.

Counsel, what is your housekeeping -- I wasn't going anywhere just yet. What is your housekeeping matter?

MR. DRESNER: I just wanted to raise the matter of the Apotex joinder motion with Hospira's motion that you already granted. I didn't hear Your Honor refer to it when you talked earlier about the motions regarding inequitable conduct.

THE COURT: It would be the same ruling. I would see no reason --

MR. DRESNER: I would assume so. Thank you very much, Your Honor.

THE COURT: That's fine. You should do that. That is granted as to both parties.

You are all, I am sure, aware of my practice with regard to objections that have been raised. They are summarily overruled, rejected, without prejudice to your ability to raise them, those that you really think need to be raised, other than the ones you have already raised in the form of motions in limine, in realtime.

But those objections are overruled. There is no way that we have the time to deal with them individually. And I am sure you understand that.

Again, I want to urge counsel, during the conduct of the trial, to keep in mind that this is a Bench trial. You preserve your positions, for sure. But in terms of atmospherics or that kind of thing or things that you might otherwise in front of a jury feel a jury shouldn't hear, keep in mind, you have got a, by now, rather thick-skinned Judge on the Bench, who is used to hearing stuff that a fact-finder maybe shouldn't hear exactly.

So just use some perspective. Keep some perspective on things.

In the proposed final pretrial order, is there anything we need to talk about?

MR. PAPPAS: Your Honor, there is one issue we would like to discuss and get Your Honor's views on it.

The parties have a disagreement about the allocation of time. We will get to time in a minute, I guess, with Your Honor's schedule.

But I just want to make clear why we truly need where one part of the case is 50 percent of the time. We think, quite frankly, the suggestion of thirds is an attempt to keep us from presenting our case.

Your Honor will recall by way of history that initially this case was --

MR. HURST: Actually, this might be -- we had a discussion on this side. We are happy with a 50-50 split.

MR. PAPPAS: That sort of takes care of that.

THE COURT: Remind me how many days we allocated?

MR. PAPPAS: Your Honor, if I can address that next.

Initially, when it was just plaintiffs versus Hospira, you put it in for seven days. In January of this year, you consolidated the cases. And, Your Honor, we agreed that consolidation made sense, particularly in view of the docket issues that the Court faces.

THE COURT: What is the day we start?

MR. PAPPAS: We start on October 26th, at least according to the current schedule we have been given.

Now, Your Honor, even with consolidation, though, we have, we, the plaintiffs, have two cases.

THE COURT: How many days do you think you need, Mr. Pappas?

MR. PAPPAS: We think it would take ten days.

THE COURT: To try the case collectively?

MR. HURST: I don't think so, Your Honor.

THE COURT: How many days do you think?

MR. PAPPAS: Can I tell you why I think ten days, Your Honor?

THE COURT: Go ahead.

MR. PAPPAS: When Apotex was added, so you have

a new party, all right, seven days against Hospira, we are only asking for three additional days.

THE COURT: Only three days, Mr. Pappas? Is that all you are asking for?

MR. PAPPAS: I understand, Your Honor. Actually, I expect that there might be other responses from the Court. But that's fine.

What we have here is a situation where, with the addition of Apotex, they have -- these parties' products are different -- my client finds themselves in a position where we have to prove not one but two infringement cases. So the effect of the consolidation, while still streamlining and making sure the Court doesn't have to have two trials, we have two infringement cases to try.

In addition, with respect to the allegations of invalidity in terms of anticipation, obviousness, there are more allegations. There are some allegations between Hospira and Apotex that are common. But there are nine raised, obviousness combinations raised by Hospira, four raised by Apotex, and five that are common as to both.

Once again, where we find ourselves is, if it was just Hospira, we would have nine allegations of obviousness. We have four new ones with Apotex. With Apotex, they have six alleged anticipatory references. Hospira has four. With the addition of Apotex, there are

two more.

Apotex adds the obviousness/double patenting as a basis of invalidity, which Hospira does not.

Now, as to each of these, Your Honor, I don't really want to trespass on the Court's time and argue about how complex or not complex they are, the parties may differ about this, but as the plaintiffs, we have to answer each one of these.

With respect to indefiniteness, Hospira has two new grounds of indefiniteness that are not raised by Hospira. With respect to best mode, Hospira does not raise best mode. Apotex raises two allegations of best mode.

And with respect to inequitable conduct, there are three allegations that are common to Hospira and Apotex, but Hospira has three of its own, Apotex has three more that are different than Hospira's.

The only way I knew how to do it, Judge, was to basically look at the issues.

All I am saying is, with those additional issues that we have to answer, attacking the invalidity and whether or not we committed inequitable conduct, and the fact that the consolidation with Apotex added a second infringement case, we respectfully believe that we need and are asking for ten days.

It's always possible it may not be needed. But,

Your Honor, the reason ten days becomes very important is because with a 50-percent now-agreed-upon allocation of time, it goes into our planning purposes for dividing the witnesses.

But I can tell Your Honor, we have streamlined our experts. They aren't going to be duplicative. They are bringing new evidence that we believe you need to hear.

But, respectfully, we simply need a chance to meet both parties. As you can see, what's already happened in terms of the work on the plaintiffs -- it's a burden we accept -- even on the in limines, we filed two but we had to respond to ten. Now, had this only been a case against Hospira, under your rule, the maximum number we would have had to respond to is five.

We are not taking issue with the fact that they filed them. All I am trying to indicate to you in as clear a way as I can is that the addition of Apotex has added issues to the case and an additional infringement case. And all -- I don't want to draw the same response.

We are simply requesting three additional days other than the seven so we can make sure we can do it all at once.

THE COURT: Hold on.

Mr. Hurst, what is your position?

MR. HURST: My view is, I have had the recent

experience before Your Honor where we did an ANDA case that was no more complicated than this that had infringement, invalidity, and we did it in five days. There is an extra party with a different product. My expectation is it should not take more than two days, a day per side. So seven days is what seems reasonable from our perspective.

Mr. Pappas talked a lot about the different defenses that the defendants are raising. We are coordinating. We are going to work together a lot better than we did on the motions in limine, Your Honor. We going to try to streamline things so you are hearing arguments about defenses just once and often possibly even from just, you know, one expert will address an issue rather than us putting up an expert and them putting up a duplicative expert.

So I do think seven days is reasonable. We will work together to take our three and a half days and make sure both parties can get our case in in three and a half days.

THE COURT: Here is what I will do. I really don't have the time. I am going to allow the possibility, depending upon how things go, that we may move a couple of things to give you nine days. I can't give you ten. I just don't have ten days to give you. That is the best I can do. That is only conditioned upon us assessing as we move along

how the time is going.

But, Mr. Pappas, normally I wouldn't give you more than ten days in a case like this for a jury trial. This is a Bench trial. We should be much more efficient on the presentations. And we can work longer than if we had a jury.

MR. PAPPAS: We can go with nine days, and I would appreciate it.

May I ask a clarification? The parties may not need it, but at least in terms of allocating time for our witnesses and stuff, can we at least use, for both of our cases against the opponents, plan to fit our witnesses into 4.5 days?

MR. HURST: Your Honor, actually, this is a very, very big issue. I have had this --

THE COURT: I thought you agreed on 50-50.

MR. HURST: We did agree on 50-50. But this is a different issue.

The parties have a disagreement on the order of proof. Traditionally, of course, the party with the burden goes first on a particular issue. That's always been the case for a lot of reasons, including it doesn't make sense to allow one party to shoot at a target before the target has been presented.

Our proposal is -- Sanofi's proposal is they go

first not only on infringement, which is their burden, but they also go first on the patent validity issues and the inequitable conduct issues, which are our burden.

So we propose the party who has the burden of proof goes first on the issue and presents the defense.

Let me say one extremely important point. Mr. Pappas just went through a series of, you know, isolated issues on obviousness when we are going to try to streamline and pull them together. He will be shooting at targets that don't exist if he goes first on it. It doesn't make an awful lot of sense.

Our proposal is the party with the burden of proof goes first on a particular issue.

THE COURT: I think it makes for a more logical presentation to the finder of fact as well.

MR. PAPPAS: Your Honor, what we were trying to do was to streamline the trial.

What Hospira and Apotex are proposing is four rounds, four rounds of the trial. Let me tell you, this is what they say. Round 1 would be Sanofi, us, presents the infringement case. Round 2 would be Apotex and Sanofi present invalidity, unenforceability, and they rebut infringement. Round 3 would be Sanofi replies on invalidity and unenforceability, or offers our defense, and then replies, has our rebuttal case, if you will, on

infringement. Then Round 4, the defendants reply on invalidity and unenforceability.

As I understand it, that's what they put in their pretrial order. This is their four rounds. And so, what we have offered as an alternative -- it's absolutely consistent with all the issues I have given you -- is that we would go first on infringement as to both parties, and to the extent the pretrial order and proposed findings of fact and conclusions of law are clear enough that we can see that they will present evidence on invalidity, such as where they are -- they take the same position, we have read their expert reports, we would put on our testimony on that.

Then the defendants would go, reply to infringement, make any other points they want to make on invalidity and the inequitable conduct case. And then the third round would simply be any rebuttal, and it would have to be proper rebuttal, by us.

I say that only, Your Honor, because it is a nonjury case. And we were just thinking of, in terms of a more orderly presentation.

Let me tell you what happened with the four rounds. Two of Apotex's experts, Kibbe and Williams, and both of Hospira's spirits, Drs. Myrdal and Calvert, plan to testify about anticipation, obviousness, indefiniteness, enablement, inequitable conduct, and their other two

witnesses, Calvert and Penson, both doctors, will testify about some of the same issues. And some of them will be covering infringement as well.

So what will likely happen in the four rounds is that these experts will go on, come off, come back later, go on, and come off.

And it's just been my understanding that often courts like to hear from the experts to the extent they can all at once to assess credibility.

THE COURT: That has been the practice.

MR. PAPPAS: I say that, this is a suggestion the plaintiffs are making, understanding that we are prepared to put on our, if you will, defenses to invalidity and inequitable conduct out of order in a way that I, quite frankly, wouldn't propose in front of a jury.

This is nonjury. Judge Sleet, you could keep it --

THE COURT: You can keep it straight. That is fair.

MR. HURST: What I just heard is a slightly different variation on Sanofi would go first on invalidity, and he said we just pick the core issues that we know are common. That just means going first on invalidity. The problem with that kind of presentation is you are shooting at a target that has not yet been erected. There is a

reason the party with the burden of proof goes first. You will hear our arguments on invalidity. You will find them persuasive or non-persuasive. You will have an idea for what you find to be the most compelling. And, frankly, Mr. Pappas and his group will hear what we have to say and shoot at what they find to be the most effective.

The party with the burden of proof typically goes first, and that's all we are proposing.

With respect to the four rounds, Your Honor, this is what we are proposing, just to simplify it.

Sanofi goes first on infringement because they carry the burden of proof. Then we get up and put on our case on both infringement, invalidity, unenforceability. Sanofi gets, obviously, to reply on invalidity and inequitable conduct, and also they obviously get a reply on infringement if they want one. At that point, Your Honor, the trial will be largely over.

If we have somebody else, my expectation for a fourth round would be to say to Your Honor, here is the issue that we would like to put an issue up on rebuttal, Your Honor, and we would narrow it to whatever you feel would be helpful, and we would ask for permission to put another witness on, to the extent we get there, because, of course, we wouldn't have had a chance to rebut on invalidity.

All we are asking for is that traditional burdens of proof be adhered to, and we think that's the most effective way to present the case from both sides' perspective.

MR. DRESNER: One more point, Your Honor. What Mr. Hurst just described as putting on our case with respect to our burden of proof, we would do that together. We would do that collectively. We wouldn't be wasting time by having Hospira do it and then Apotex do it. We are going to work together on this because there are, as you have heard Mr. Pappas say, a whole lot of overlapping issues.

THE COURT: Mr. Pappas.

MR. PAPPAS: Your Honor, this is obviously a matter, as are many of the things in trial, that is left to your own discretion. Obviously, whichever way you want to proceed is fine with us.

My answer is, what I think I heard was maybe not four rounds, really three rounds --

THE COURT: I think that's what you heard.

MR. PAPPAS: -- with the possibility of rebuttal. Your Honor, we think our proposal is better.

THE COURT: Mr. Pappas, that seems to be a reasonable compromise between the parties on this issue. And that's what I will do.

MR. PAPPAS: Your Honor, that is fine. Our

presentation, just so Your Honor understands, the presentation of our case on infringement and the inventors and how the story took place, normally in that presentation, we may discuss some of the more critical pieces of prior art, just so we can explain them in the context of the invention.

THE COURT: That is fine.

MR. PAPPAS: Because there are no bright lines on this.

THE COURT: I think that's right. I think Mr. Hurst is looking for mischief there.

MR. HURST: Obviously, there are limits on what happens, and we will see how it plays out, Your Honor. But I understand your ruling. We are not going to jump up every time they mention anything relating to invalidity.

THE COURT: Thank you. Good.

Counsel should keep also in mind that, while teachers will tell you that repetition is a good thing for learning, be careful about how much repetition you have.

MR. PAPPAS: I understand.

THE COURT: It can become a negative.

MR. PAPPAS: Your Honor, may I raise something, in light of the streamlining process and getting some guidance from Your Honor?

This is another issue. Hospira has put down in

their possible witnesses, they have listed 34 may-call, live, or by deposition witnesses.

If these witnesses had been deposed, we don't have any objection. However, to the extent Hospira and/or Apotex are going to attempt or intend to try to call live witnesses that were not on their 26(a) disclosures, then we will object.

We don't know if we are going to have an issue. But we would like some guidance from Your Honor, because, quite candidly, Your Honor, in getting ready for a trial three and a half, four weeks from now, we don't think it's fair to have to prepare potential crosses for 34 witnesses that are in this "may call live" category. It seems to me at this juncture we are asking for the Court's assistance here if possible to get some narrowing.

And maybe we don't have an issue. Maybe the only witnesses Apotex and Hospira intend to call live are ones they identified on their 26(a)(1) disclosures. If so, that's fine. But if they are intending to call witnesses that they didn't put on their 26(a)(1) disclosures, then we do object.

We would just like to know if we have an issue about this and to avoid morning conferences on the first day of trial.

MR. ALY: Your Honor, there are a number of

witnesses. The source for the number of witnesses that were on that list are either our initial disclosures, people who were deposed, people who are in our interrogatories, and the fourth category -- I think this is where if dispute lies -- people who are on Sanofi's initial disclosures but then now they have decided for one reason or another to not call those particular witnesses in that fourth category.

To that extent, if that is all they are asking for, is for specific witnesses that were on their initial disclosures but we shouldn't call them, we have tried twice to reach out to them by e-mail over the last week to say, what is it that you are asking for in terms of this relief? Because maybe we will agree on something and we won't waste Court's time with it. They didn't respond to either those e-mails, Your Honor. I think Mr. Pappas is correct, there might be agreement here. There might be an issue with rebuttal on authentication, those kind ever things. But in general I think we are all on the same page.

THE COURT: I am not going to delve into this any further. Counsel, you are going to have to talk about this.

MR. PAPPAS: Very well, Your Honor. We at least wanted to surface the issue. Hopefully, we will be able to work it out.

THE COURT: Just for a moment, let's revisit the

amount of time we are going to need, and do it with this information to plug into your computers.

What we should plan on is a 9-to-5 day, with an hour for lunch. We will all need bio breaks in the morning -- I will, anyway, I will speak for me --

MR. PAPPAS: We will, Your Honor.

THE COURT: -- in the morning and the afternoon.

MR. PAPPAS: I will speak for the plaintiffs. We will.

THE COURT: So we are going to get at least six and a half hours of trial time a day. Multiplied by, let's use seven right now as the multiplier, whatever that comes out to. I don't know what it comes out to.

MR. ALY: Forty-five and a half.

THE COURT: Divided in half.

Mr. Pappas, you were the one who wants the additional time. What's your reaction to that?

MR. PAPPAS: Your Honor, in preparation for today, we have tried to get a handle on likely witnesses and witnesses we think the defendants are going to call. Our best estimate at this time is we need about 30 hours, counting our directs and cross, to meet both cases.

Again, Your Honor, that is an estimate at this point, because we don't know exactly who the defendants are going to call and how long the examinations will go on. We

tried to make some rough estimates.

THE COURT: These are guesstimates.

Mr. Hurst, did you want to chime in?

MR. HURST: Our expectation was we could actually get our case done in three and a half days, 21, 22, 23 hours. That is what we thought we could do. Obviously, it does depend on how many witnesses sanofi calls. Our expectation is they probably are not going to call all seven experts. But if they were going to do that, that takes more time.

THE COURT: I think we are going to be fine on time. I don't think time is going to be an issue.

But you are going to need to talk about this issue of this identification of witnesses.

MR. HURST: On both sides, Your Honor.

We did reach one agreement, I don't want to take up your time with this because we actually have an agreement on it, but make a gloss on it.

We have agreed that two days, 6:00, two days before a witness gets on the stand , that we tell each other, so we will have time to prepare for that two days, and that the day before we give each other, 6:00 the night before we give each other any administrative exhibits we are going to use and identify what exhibits we expect to use with the witness.

I often give my witness order to the other side as far as in advance as I can, and I imagine we could do that because it would help streamline things from both sides and reduce the workload as well.

THE COURT: Mr. Pappas.

MR. PAPPAS: Your Honor, we will certainly cooperate in every way we can. I think what Mr. Hurst and I worked out this morning was the agreement two days before you get the witnesses, the day before the exhibits, and also the day before any demonstratives.

So the parties have reached agreement on that this morning even before the courtroom was open.

MR. DRESNER: Mr. Pappas is correct on that. That is the agreement that we reached this morning. If we can cooperate to do something else, we will consider streamlining the case.

MR. HURST: We would like more notice.

THE COURT: I understand that. If you can agree on additional notice -- but you have an agreement, and you can certainly improve on it if you want. That is fine.

All exhibits are in. So you don't have to move, unless you want to raise objections.

MR. PAPPAS: Your Honor, the parties are trying to work on a common, sort of a joint, I guess, exhibit list, that puts them all together. Does Your Honor have a

preference about whether you would like that list just in written form or whether or not you want it CD form?

THE COURT: A writing, it seems to me, is fine, with a CD.

MR. HURST: Would notebooks per witness be useful to Your Honor?

THE COURT: Notebooks per witness are useful. Absolutely.

MR. HURST: As opposed to giving you a huge number of binders.

THE COURT: That's typically what I see. They are useful. I do find them useful.

We are going to give them back to you.

What else, counsel?

MR. HURST: Last thing. Opening statements, I understand Your Honor prefers short opening statements.

THE COURT: I do.

MR. HURST: Just some guidance on that? Forty-five minutes? There is a lot of different defenses. My expectation is that would be kind of useful. That range, 45 minutes, 50 minutes, does that sound reasonable to Your Honor?

THE COURT: That sounds like just about at the limit of where you need to be.

MR. HURST: Thank you, Your Honor.

I am not going to have closing speeches, just so you know.

What else?

MR. HURST: I had one more request. This particular inventor that we would love to see live here and we are not sure if it is going to be possible.

THE COURT: That raises one issue just for a second.

What is your plan with regard to non-live testimony?

MR. HURST: My expectation is we would give it to you in written form with the highlighted portions that we want to designate. And we are going to try to compress that as much as possible. If there is particular testimony -- and this actually related to that issue that I just raised -- if there is particular testimony from a deposition that we think is particularly important, we might ask for leave to play a short portion. I am talking three-, five-minute type clips in court. That was our expectation, if that works for you.

THE COURT: My principal concern is that you don't plan on reading to me.

MR. PAPPAS: Your Honor, that would be our proposal as well, to give it to you in video form, certainly not read to you. But we may also have segments that we

think are important, to give you context about how the witnesses are testifying. So we would do the same. But we can't tell you about the length. But we have our clock. We are going to use it very carefully.

MR. HERRMANN: Is Your Honor counting any time towards the deposition contributions?

THE COURT: That I am going to view privately?

MR. HERRMANN: Yes.

THE COURT: No. I am not going to count that against the parties. That is Court time. I don't know how I would even estimate that, quite frankly.

MR. HURST: There is a particular inventor that we would like to see live if possible here. I guess my question here is whether we can have some order, giving us notice on whether that person is going to be here live sooner rather than later, because it is particularly important to us for trial purposes. It's Bombra.

MR. SIPES: We expect that Mr. Bombra will be here.

Here is the challenge for us. We expect him to come. None of them, none of the three inventors presently work for the company, so we don't have control over them. We expect that they will come. They have raised issues, for example, about travel, if they are elderly, if there is swine flew in the United States.

I can't force him to come if he will not come. But we are endeavoring to get Mr. Mr. Fabre's cooperation. All three of the inventors are French citizens and they live in France.

MR. HURST: And French speakers as well, so you will have translations in court.

MR. PAPPAS: Which, Your Honor, just to point out, and I forgot to mention, is another reason that we added some time into our 30 hours, because it has been my experience that when you have translators it just takes longer.

THE COURT: Well, it usually takes a little longer.

MR. SIPES: We will try to work with the French speakers to expedite it as much as possible.

THE COURT: We have translations all the time in this Court.

MR. HURST: Just on the inventors, can we get notice when they know that they are actually going to be coming to trial? That is my request. It is a big trial preparation issue for us to prepare cross-examination for inventors. It takes a lot of time and effort. And two days before does not work.

THE COURT: I should think that would be the professional way to approach it. You are all professionals.

So as soon as it is known, the status of whether the witness will be live or not, that should be made known.

MR. SIPES: We would certainly provide that courtesy. We would expect the same courtesy.

THE COURT: That underlies this Court's expectation, that lawyers will be civil with one another and treat one another that way. You are officers of the Court. So you have that obligation, not just to win, but to maintain your credibility with this Court. You are going to be back this way. All of you have been here before.

Keep that in mind. Certainly, Delaware counsel should keep that in mind.

Okay. What else? Anything?

MR. PAPPAS: Nothing from the plaintiffs, Your Honor.

THE COURT: Counsel, have a good day. Take care.

(Counsel respond "Thank you.")

(Conference concluded at 12:20 p.m.)

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Reporter: Kevin Maurer